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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,174	01/14/2004	Willi Kaiser	31-HL-5510(5024-00126)	4195
26753	7590	04/26/2006		
ANDRUS, SCEALES, STARKE & SAWALL, LLP 100 EAST WISCONSIN AVENUE, SUITE 1100 MILWAUKEE, WI 53202				
			EXAMINER OROPEZA, FRANCES P	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/757,174

Applicant(s)

KAISER ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 1/14/04 (Initial Filing).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/14/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It appears claim 5 is redundant of claim 1, and claim 5 should be deleted.

In claim 12, line 3, "the analysis" lacks antecedent basis.

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-6, 9-13 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rohde (US 5876351) in view of Wang (US 5967994), known hence as Wang ('994).

Rohde teaches the monitoring of electrocardiograms using a portable modular diagnostic medical device comprising an electrocardiogram (ECG) cartridge (12) with an input terminal and leads, an instrument amplifier (62), an analog to digital converter (72), memory, and a screen (20). Waveforms from individual leads can be viewed on the screen, and the output of the signal via the serial port permits the ECG signal to be sent via cable to a computer, the computer inherently having peripherals such as a printer and memory, the memory read as external memory. The functionality of the monitoring device can be expanded or potentially expanded, such as adding the detection of cyclic artifacts and the selection of a lead based on the lack of artifacts.

As discussed in the previous paragraph, Rohde discloses the claimed invention except for a twelve lead ECG system (claims 6, 14, 23) and an analysis module including a processor and software to detect cyclic artifact and select a lead for analysis based on the lack of cyclic artifact (claims 1, 9, 17).

Wang ('994) teaches signal characterization using a twelve lead ECG system and an analysis module, including a processor and software, to detect cyclic artifact and to select a lead for analysis based on the lack of cyclic artifact for the purpose providing the optimum lead configuration for an ECG study and for the purpose of determining the signal quality of the

lead(s) sensing the ECG signal. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a twelve lead ECG system and to have used an analysis module, including a processor and software, to detect cyclic artifact and to select a lead for analysis based on the lack of cyclic artifact in the Rohde system in order to provide a high quality, comprehensive ECG signal that, based on analysis, will have minimal distortion enabling the physician to make an accurate diagnosis (fig. 6,9; col. 1 @ 8-15; col. 2 @ 40-56; col. 3 @ 37 – col. 4 @ 11; col. 4 @ 19-34, 48-57; col. 5 @ 3-17; col. 6 @ 29-36; col. 13 @ 21-25; col. 16 @ 4-16).

4. Claims 7, 15 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rohde (US 5876351) in view of Wang (US 5967994), known hence as Wang ('994), and further in view of Wang (US 6119035), hence known as Wang ('035). As discussed in paragraph 3 of this action, modified Rohde discloses the claimed invention except for the multi-lead electrocardiogram (ECG) comprising five leads (claims 15, 24) or seven leads (claim 7).

Wang ('035) teaches synthesizing an ECG using a multi-lead ECG comprising five leads or seven leads for the purpose of synthesizing a twelve lead electrocardiogram. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the multi-lead ECG comprising five leads or seven leads in the modified Rohde system in order to quickly and easily produce a user acceptable synthesized twelve lead ECG, the result of the synthesis being easily check by adding one or more other leads, the synthesized twelve lead ECG reducing the number of leads required for the ECG, hence avoiding the accurate preparation and placement of ten electrodes require for the twelve lead ECG, and reducing the significant clutter

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that arises from the wires and connects associated with each electrode (abstract; col. 3 @ 12-30; col. 4 @ 47-51; col. 6 @ 12-36, 44-53; col. 7 @ 15-31).

5. Claims 8, 16 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rohde (US 5876351) in view of Wang (US 5967994), known hence as Wang ('994), and further in view of DeLuca et al. (US 6238338). As discussed in paragraph 3 of this action, modified Rohde discloses the claimed invention except for the analog-to-digital converter being connected between the instrument amplifier and the analysis module.

DeLuca et al. teach biosignal monitoring using a component arrangement of the analog-to-digital converter (57) being connected between the instrument amplifier (55) and the analysis module (58) for the purpose of processing the electrocardiogram signal. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the analog-to-digital converter being connected between the instrument amplifier and the analysis module in the modified Rohde system in order to process the input signal such that the processing results in a larger dynamic signal range important in sampling low level biosignals contaminated with large artifacts, and to minimize the need to auto scale the gain (fig. 5; col. 3 @ 11-18, 31-38, 59-62; col. 4 @ 65 – col. 5 @ 2; col. 5 @ 48-53, 58-63).

### *Specification*

6. The specification is objected to because on page 5, line 22, it appears "FIG. 2" should be --FIG. 3--.

*Claims Objections*

7. Claim 25 is objected to because this sentence ends with two periods.

*Information Disclosure Statement*

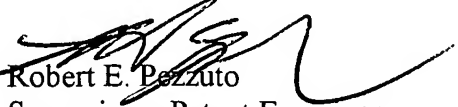
8. The information disclosure statement filed 1/14/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The two non-patent literature publications noted in the information disclosure statement, the article by Kaiser and the article by Van Alste, apparently were not submitted, hence they have not been considered. The information disclosure statement with the non-patent publications lined through has been placed in the application file, but the non-patent publications referred to therein has not been considered.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3766

*FPO*  
*4/22/06*

  
Robert E. Pezzuto  
Supervisory Patent Examiner  
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